UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TARO PHARMACEUTICALS NORTH AMERICA INC., et al., Plaintiffs, v. SUVEN LIFE SCIENCES, LTD, et al. Defendants.	Civil Action No. 11-2452 (JAP) **OPINION**

PISANO, District Judge.

I. INTRODUCTION

This is a patent infringement action brought by plaintiffs Taro Pharmaceuticals North America, Inc., and Taro Pharmaceutical U.S.A. (together, "Taro" or "Plaintiffs"), Inc. against defendants Suven Life Sciences, Ltd. and Suven Life Sciences USA, LLC ("Suven USA" or "Defendant").[1] Presently before the Court is Taro's motion pursuant to Federal Rules of Civil Procedure 12(b)(6) and 12(f) to dismiss Suven USA's inequitable conduct counterclaims (Counterclaims V and VI) and strike Suven USA's inequitable conduct affirmative defenses (fifth and sixth affirmative defenses). The Court decides the motion without oral argument pursuant to Federal Rule of Civil Procedure 78. For the reasons below, Taro's motion is granted.

[1] To date, only Suven USA has appeared in this action.

II. BACKGROUND

Taro holds approved New Drug Application ("NDA") No. 18-613 for malathion lotion, 0.5%, a pharmaceutical topical preparation which is marketed under the brand name Ovide. Ovide is approved by the Food and Drug Administration for the treatment of head lice. In early 2011, Suven USA submitted to the United States Food and Drug Administration ("FDA") abbreviated new drug application ("ANDA") No. 091559 seeking approval to engage in the commercial manufacture, use, or sale of a generic malathion lotion, 0.5%.

Taro brings the instant suit alleging that by filing its ANDA, Suven USA has infringed two of Taro's patents, United States Patent No. 7,560,445 (the "'445 patent") and United States Patent No. 7,977,324 (the "'324 patent"), both of which are entitled "Process for Preparing Malathion for Pharmaceutical Use." *See* Amended Complaint ("Compl")., Ex. A and Ex. B. The '445 patent covers methods of making highly pure malathion, and the '324 covers the purified formulation of malathion. Highly pure malathion is desirable because malathion's impurities are highly toxic to humans. Counterclaim ¶ 12.

In this action, Suven USA has asserted, *inter alia*, counterclaims and affirmative defenses alleging that the patents-in-suit are unenforceable based on inequitable conduct. Specifically, Suven USA alleges that Taro concealed and/or misrepresented material information in submissions to the Patent Office during prosecution.

A. Malathion

According to Suven USA's counterclaim, malathion was first used as a pesticide in the 1950s. Counterclaim ¶ 8. In 1982, the FDA approved malathion for use in topical pharmaceutical compositions for the treatment of lice infestations. *Id.* ¶ 9. Since then, various companies have sold malathion lotion 0.5% under the brand name Ovide. *Id.* ¶ 10.

Taro obtained the exclusive right to market Ovide in 2003 from Medicis Pharmaceutical Corporation ("Medicis"). *Id.* ¶ 11.

Malathion's impurities, particularly isomalathion, are highly toxic. Consequently, even non-pharmaceutical grade malathion used in pesticides is 96% pure. *Id.* ¶ 14. Pharmaceutical-grade malathion, such as that found in Ovide, have a much higher purity. *Id.* Taro, and Medicis before it, obtained the malathion active pharmaceutical ingredient used in Ovide products from Cheminova A/S ("Cheminova"). *Id.* ¶ 12. According to Certificates of Analysis from Cheminova, stability test results, and product specifications contained in the prosecution history for the '445 patent (and submitted in the '324 patent prosecution history), the malathion produced by Cheminova and used in Ovide beginning in the late 1990s was of very high purity. *Id.* at ¶ 15, 16.

B. Prosecution of the '445 and '324 Patents

In 2006, U.S. Patent Application No. 11/427,863 (the "'863 application") was filed, which later issued as the '445 patent. *Id.* ¶ 17. In 2009, U.S. Patent Application No. 12/353,691 (the "'691 application") was filed as a continuation of the '863 application. The '691 application later issued as the '324 patent. *Id.* ¶ 62.

As noted above, the '445 patent covers methods of making highly pure malathion, and the '324 covers the purified formulation of malathion. In support of the patentability of the methods and compositions claimed, the applicants made the following statements in the '863 application:

> The malathion prepared by the methods of this invention has significantly lower levels of toxic impurities such as isomalathion when compared with other, commercially available malathion preparations that are currently used for pharmaceutical purposes.
>
> * * *
>
> When compared with malathion from Cheminova, malathion prepared by the methods of the present invention has less isomalathion, <0.02% (w/w) versus 0.2% (w/w) isomalathion from Cheminova.

Id. at ¶ 20-21. However, Suven USA alleges that such statements are false, and that at the time they were made the applicants had in their possession documents showing that highly pure malathion was present in the prior art. *Id.* ¶ 24-26. Specifically, it it alleged that the applicants possessed Certificates of Analysis showing that malathion made in 1999 had a purity as high as 99.9% and extremely low levels of isomalathion. *Id.* The applicants also had in their possession specification for Ovide lotion dated almost two years prior to the filing of the '863 application showing that the Ovide released for sale in the United States contained less than 0.1% (w/w) isomalathion. *Id.* ¶ 23. Suven USA argues that if these documents would have been "accurately disclosed" to the Patent Office, several claims in the '445 patent and one claim in the '324 patent would have been barred as anticipated. These documents were submitted to the patent examiner in March 2009 with an amendment to the '863 application. *Id.* At the time of their submission, the applicant noted as follows: "Submitted herewith is an IDS citing additional material identified during review of Applicants' files. This material is submitted for completeness, although it is believed to be cumulative of reference already of record." *Id.* ¶ 52.

C. Data Presented in Table III

The '863 application contained a table comparing the purity of malathion prepared by the process of the invention with prior-art malathion. *Id.* ¶ 29. As described in the application, when compared with the prior-art malathion samples tested, the malathion prepared by the process of the invention had fewer impurities such as isomalathion. *Id.*; *see also* '863 application attached as Ex. A to Catenacci Decl. These results are set forth in Table III of the application. The table shows, for example, that malathion prepared by the claimed method contained <0.02% (w/w) isomalathion while the samples from Cheminova contained 0.2% (w/w) isomalathion.

Suven USA asserts that the data in Table III is "false and misleading." Def. Brf. at 6. It alleges that the isomalathion content in all of the Cheminova samples analyzed were inconsistent with the Certificates of Analysis and the Ovide product specifications in possession of the applicants. Suven USA notes that this discrepancy may be explained by the fact that the Cheminova samples were at least one year old, and that malathion degrades over time, which would result in a higher level of impurities. Counterclaim ¶ 31, 36. Indeed, Table III contains a footnote, designated by three asterisks, alerting the reader that the Cheminova samples were "stored for at least 1 year under proper storage conditions prior to analysis." *Id.* ¶ 31. According to Suven USA, the samples made by the claimed process, however, were fresh. *Id.* ¶ 30. Thus, Suven USA asserts that the comparison in Table III is misleading because it used fresh samples on the one hand and at least one-year-old samples on the other.

III. ANALYSIS

A. Legal Standard Under Rule 12(b)(6)

Under Federal Rule of Civil Procedure 12(b)(6), a court may grant a motion to dismiss if the complaint fails to state a claim upon which relief can be granted. The Supreme Court explained the standard for addressing a motion to dismiss under Rule 12(b)(6) in *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 562, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). The *Twombly* Court stated that, "[w]hile a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, ... a plaintiff's obligation to provide the grounds of his entitle[ment] to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do[.]" *Id.* at 555 (internal citations omitted); *see also Baraka v. McGreevey*, 481 F.3d 187, 195 (3d Cir. 2007) (stating that standard of review for motion to dismiss does not require courts to accept as true "unsupported conclusions and unwarranted inferences" or "legal conclusion[s] couched as factual allegation[s]." (internal quotation marks omitted)). Therefore, for a complaint to withstand a motion to dismiss under Rule 12(b)(6), the "[f]actual allegations must be enough to raise a right to relief above the speculative level, ... on the assumption that all the allegations in the complaint are true (even if doubtful in fact) ..." *Twombly*, 550 U.S. at 555 (internal citations and footnote omitted).

The Supreme Court has emphasized that, when assessing the sufficiency of a civil complaint, a court must distinguish factual contentions and "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements." *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937, 1949, 173 L.Ed.2d 868 (2009). When evaluating a motion to dismiss for failure to state a claim, district courts conduct a three-part analysis.

> First, the court must "tak[e] note of the elements a plaintiff must plead to state a claim." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1947 (2009). Second, the court should identify allegations that, "because they are no more than conclusions, are not entitled to the assumption of truth." *Id.* at 1950. Third, "whe[n] there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement for relief." *Id.* This means that our inquiry is normally broken into three parts: (1) identifying the elements of the claim, (2) reviewing the complaint to strike conclusory allegations, and then (3) looking at the well-pleaded components of the complaint and evaluating whether all of the elements identified in part one of the inquiry are sufficiently alleged.

Malleus v. George, 641 F.3d 560, 563 (3d Cir. 2011). A complaint will be dismissed unless it "contain[s] sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570). This "plausibility" determination will be "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Fowler*, 578 F.3d at 211 (citations omitted). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully;" mere consistency with liability is insufficient. *Iqbal*, 556 U.S. at 678. A plaintiff may not required to plead every element of a prima facie case, but he must at least make "allegations that raise a reasonable expectation that discovery will reveal evidence of the necessary element." *Fowler*, 578 F.3d at 213 (3d Cir. 2009).

B. Legal Standard Under Rule 12(f)

Federal Rule of Civil Procedure 12(f) provides that a court "may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." An affirmative defense is insufficient if "it is not recognized as a defense to the cause of action." *FTC v. Hope Now Modifications, LLC*, 2011 WL 883202 (D.N.J. March 10, 2011) (quoting *Tonka Corp. v. Rose Art Indus., Inc.*, 836 F.Supp. 200, 217 (D.N.J.1993)).

"[A]n affirmative defense can be stricken only if the defense asserted could not possibly prevent recovery under any pleaded or inferable set of facts." *Id.* at *2 (quoting *Tonka Corp.*, 836 F.Supp. at 217).

C. Inequitable Conduct Claims and Affirmative Defenses

Suven USA alleges that the facts described above, as set forth in their counterclaim, state a claim for inequitable conduct. Suven USA's claim, in essence, is based upon allegations the applicants had in their possession documentation that showed their invention was anticipated under the prior art, the applicants falsely stated that the alleged invention has less isomalathion than the prior art; and the applicants submitted false and misleading test data in Table III as a result of comparing fresh samples to old samples.

"Inequitable conduct is an equitable defense to patent infringement that, if proved, bars enforcement of a patent." *Therasense, Inc. v. Beckton, Dickinson and Co.*, 649 F.3d 1276, 1285 (Fed.Cir.2011) (en banc). Applicants are required to prosecute their patents with candor, good faith and honesty, and breach of this duty, including acts such as "affirmative misrepresentation of material fact, failure to disclose material information, or submission of false information, coupled with an intent to deceive," constitutes inequitable conduct. *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995). The Federal Circuit has described the remedy of inequitable conduct as the "atomic bomb" of patent law. *Id.* at 1288. While validity defenses, for example, are claim specific, a finding of inequitable conduct as to any single claim renders the entire patent unenforceable. *Id.* Inequitable conduct "cannot be cured by reissue … or reexamination … [and] can render unenforceable other related patents and applications in the same technology family." *Id.* Because of these and other far-reaching consequences, the Federal Circuit has noted that "charging inequitable conduct has become a

common litigation tactic," and has referred to inequitable conduct claims as a "plague[]," claims that are "overplayed" and often brought on "the slenderest of grounds." *Id.* at 1289.

Finding that "the inequitable conduct doctrine has plagued not only the courts but also the entire patent system," the court in *Therasense* tightened the standards for proving inequitable conduct. There are two essential elements to a claim of inequitable conduct, and these must be shown by clear and convincing evidence. The first is intent to deceive, which, when sought to be proven by circumstantial evidence, must be "the single most reasonable inference able to be drawn from the evidence." *Id.* at 1287, 1290. The second element is materiality, and the materiality required to establish inequitable conduct is "but-for" materiality. *Id.* at 1291.

While *Therasense* established a more stringent standard for proving inequitable conduct, the decision did not address whether *Therasense's* more stringent standards (*e.g.*, whether intent to deceive must be the single most reasonable inference able to be drawn) should apply at the pleading stage. It appears that it should not. In a post-*Therasense* decision, the Federal Circuit applied the pleading standard as set forth in *Exergen v. Wal–Mart Stores, Inc.*, 575 F.3d 1312, 1318, 1330 (Fed. Cir. 2009), noting that a "charge of inequitable conduct based on a failure to disclose will survive a motion to dismiss only if the plaintiff's complaint recites facts from which the court *may reasonably infer* that a specific individual both knew of invalidating information that was withheld from the PTO and withheld that information with a specific intent to deceive the PTO." *See Delano Farms Co. v. Ca. Table Grape Comm'n*, 655 F.3d 1337, 1350 (Fed. Cir. 2011) (emphasis supplied) (citing *Exergen* and *Therasense*).

A claim for inequitable conduct must be pled with particularity pursuant to Federal Rule of Civil Procedure 9(b). *Ferguson Beauregard/Logic Controls, Div. of Dover Resources, Inc. v. Mega Sys., LLC,* 350 F.3d 1327, 1344 (Fed. Cir. 2003). As summarized in *Exergen*, in order to survive a motion to dismiss,

> the pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the [Patent Office]. Moreover, although "knowledge" and "intent" may be averred generally, a pleading of inequitable conduct under Rule 9(b) must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the [Patent Office].

575 F.3d at 1328-29.

In the present case, with respect to the heightened pleading requirement of Rule 9(b), Taro does not seriously contend that Suven has failed to plead the relevant facts with the requisite specificity. Rather, Suven USA contends that the facts pled do not state a claim for inequitable conduct. The Court agrees that they do not.

Suven USA's counterclaim is centered on two sets of items that are contained in the file histories of the patents-in-suit: (1) the data in Table III of the '863 application; and (2) Cheminova's certificates of analysis and Ovide's product specifications. With respect to Table III, which summarized the analysis of the impurities in malathion produced by Taro's process and malathion made by Cheminova, Suven USA alleges that Taro made a misleading comparison because Cheminova samples were old and Taro's samples were fresh. However, the table specifically directs the reader to a footnote (designated with three asterisks -- "***") that clearly and unequivocally states that the Cheminova samples were at least one year old.

The footnote notes that the Cheminova samples "were stored for at least 1 year under proper storage conditions prior to analysis." Counterclaim ¶ 31.

Suven USA also alleges that Table III is false apparently because its data allegedly differs from the Cheminova Certificates of Analysis and the Ovide product specifications. However, the applicant told the Patent Office that impurity levels in malathion increase over time. See '445 patent, col. 2, lines 2-3 ("Some of the impurities are formed as breakdown products during storage"); lines 8-10 ("[D]uring storage, malathion can convert to isomalathion …"); lines 28-29 ("malathion breaks down into toxic by-products during storage"). The unambiguous footnote as well as these clear representations to the Patent Office undercut Suven USA's claim that the applicants' materially mislead the Patent Office and, given such facts, the Court cannot reasonably draw an inference that the applicants had the requisite intent to deceive the Patent Office.

The Court likewise finds that Suven USA's inequitable conduct claim finds no support in the allegations that the applicants made statements to the Patent Office that, although consistent with the data in Table III, were allegedly at odds with the data in the Certificates of Analysis and Ovide product specification. The applicants submitted Certificates of Analysis and product specification to the Patent Office during prosecution, and these documents were considered by the examiner. *See* Catennacci Decl. Ex. D. The facts simply do not support the inference that Suven USA would have the Court draw that the applicants tried to mislead the Patent Office by "dump[ing]" a "mass of technical data" (*i.e.*, the Certificates of Analysis and product specification) on the Patent Office at the "eleventh hour." Def. Brf. at 7, 11. Rather, the documents in question comprised a mere 12 pages of not-particularly-dense data, *see* Catennacci Decl. Exs. B, E, and no other references were submitted along with these 12

pages, *id.* Ex. D. The examiner had all of the relevant materials before him, expressly considered them, and the office granted the patent.

The decision *in Rohm & Haas Co. v. Crystal Chemical Co.*, 722 F.2d 1556 (Fed. Cir. 1983), a case relied upon by Suven USA, is factually distinguishable and does nothing to alter the Court's conclusion that Suven USA's inequitable conduct claims and defenses fail. In *Rohm & Haas*, the patentee submitted affidavits that falsified data and failed to accurately represent the experimental conditions used in studies submitted to the Patent Office. *Id.* at 1570–71. The court held that such material misrepresentations were not cured by the patentee's presentation to the patent examiner of "a mountain of largely irrelevant data from which he [was] presumed to have been able, with his expertise and with adequate time, to have found the critical data." *Id.* at 1573. Under such circumstances, the Federal Circuit found it to be "unrealistic" that the patent examiner would be "fully informed" of all material factors relevant to patentability. *Id.* Here, there is no allegation that Taro falsified any data, and the experimental conditions underlying the data in Table III were clearly disclosed to the examiner. Furthermore, rather than a "mountain" of over 3,700 pages of data as was produced in *Rohm & Haas* a decade after the original application was filed and prosecution had been completed, Taro submitted a mere 12 pages of data during prosecution that the examiner clearly considered.

Suven USA further argues that the portions of its fifth and sixth affirmative defenses and Counterclaims V and VI that allege unclean hands should survive as an alternative basis for asserting that the patents-in-suit are unenforceable because the applicants engaged in "egregious misconduct." While "as a general matter, the materiality required to establish inequitable conduct is but-for materiality," the *Therasense* court recognized an exception to

this general rule in "cases of affirmative egregious misconduct." *Therasense*, 649 F.3d at 1291-92. Such cases do not require a showing of materiality because where a party engaged in a "deliberately planned and carefully executed scheme," materiality is assumed. *Id.* Thus, the exception essentially retains the unclean hands defense from which the inequitable conduct doctrine originated. *Id.* at 1293.

Here, the Court finds that Suven USA's counterclaims are devoid of factual allegations that could be characterized "affirmative egregious misconduct." As the *Therasense* court noted, acts that may constitute affirmative egregious misconduct involve "deliberately planned and carefully executed scheme[s] to defraud." *Id.* at 1292. Early unclean hands cases that dealt with egregious misconduct involved perjury, the suppression of evidence, the manufacture of evidence, and bribery. *Therasense*, 649 F.3d at 1292-93 (citing the following as examples of egregious misconduct: *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 65 S.Ct. 993, 89 L.Ed. 1381 (1945) (perjury and suppression of evidence); *Hazel–Atlas Glass Co. v. Hartford–Empire Co.*, 322 U.S. 238, 64 S.Ct. 997, 88 L.Ed. 1250 (1944) (manufacture and suppression of evidence), overruled on other grounds by *Standard Oil Co. v. United States*, 429 U.S. 17, 97 S.Ct. 31, 50 L.Ed.2d 21 (1976); *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240, 54 S.Ct. 146, 78 L.Ed. 293 (1933) (bribery and suppression of evidence). Suven USA's claims simply do not allege facts that involve conduct of the quality and character that would be required to fall into *Therasense's* materiality exception. As such, Suven USA's inequitable conduct counterclaims are dismissed in their entirety, and Suven USA's inequitable conduct defenses are similarly stricken.

IV. CONCLUSION

For the reasons above, Taro's motion to dismiss Suven USA's counterclaims V and VI and to strike the fifth and sixth affirmative defenses is granted. An appropriate Order accompanies this Opinion.

/s/ JOEL A. PISANO
United States District Judge

Dated: June 28, 2012